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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/556,390 04/24/00 YOUNG

K 1142.0081-03

025291 HM22/0705  
AMERICAN HOME PRODUCTS CORPORATION  
PATENT SECTION  
FIVE GIRALDA FARMS  
MADISON NJ 07940-0874

EXAMINER

SCHWARTZMAN, R

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/556,390

Applicant(s)

YOUNG ET AL.

Examiner

R. Schwartzman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43,45-51 and 53-57 is/are allowed.
- 6) ☒ Claim(s) 1-42,44,52,58-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

ZETA ADAMS  
PATENT ANALYST  
*Zeta Adams*

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *crf report*.

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### **DETAILED ACTION**

This Office action is in response to the application filed April 24, 2000. Claims 1-69 are pending in this application.

#### ***Specification***

The specification contains amino acid and/or nucleic acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Raw Sequence Listing Error Report. Additionally, the specification contains sequences (pages 25, 26, 28-31, 33, 37, 39, 43, 44) which are not identified by the appropriate sequence identifier numbers. Applicant must provide a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office action must include a complete response to the requirement for a new Sequence Listing.

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In the Brief Description of the Drawings each panel of a drawing containing multiple panels must be referred to as a separate figure. The first line of each description must refer to each separate figure (*e.g.*, Figures 1A-1C). Correction is required for Figure 2.

### *Claim Objections*

Claims 7, 23, 39 and 64 are objected to because of the following informalities:

Claim 7 is objected to as the abbreviation "TGF" should be defined the first time it appears in the claims.

Claim 23, although legally proper, appears as if it should be dependent from claim 22 for consistency with the other sets of claims.

Claim 39, although legally proper, appears as if it should be dependent from claim 38 for consistency with the other sets of claims.

Claim 64, although legally proper, appears as if it should be dependent from claim 63 for consistency with the other sets of claims.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-42, 44, 52 and 58-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is vague and indefinite as it contains a step of incubating a test sample with the yeast cell but the method does not appear to involve test samples. Additionally, the claim is incomplete as it does not contain a positive process step which clearly relates back to the preamble as the last recited step is the detection of luciferase gene expression but the method is drawn to detection of peptide interactions.

Claim 32 is vague and indefinite as it is drawn to detecting the presence or absence of luciferase activity in the first and second yeast cells in step (iv) and then looking for a change in luciferase activity in one of the yeast cells in step (v). It is unclear how the change in activity in step (v) relates to the presence or absence of activity in step (iv).

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Claims 44 and 52 are vague and indefinite as it is unclear which yeast cell is being referred to since parent claim 43 is drawn to two different yeast cells.

Claim 58 is vague and indefinite as it contains a step of incubating a test sample with the yeast cell but the method does not appear to involve test samples. Additionally, the claim is incomplete as it does not contain a positive process step which clearly relates back to the preamble as the last recited step is the detection of luciferase gene expression but the method is drawn to detection of peptide interactions.

Claim 59 is vague and indefinite as it is unclear which yeast cell is being referred to since parent claim 58 is drawn to two different yeast cells.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13, 14, 29-39, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields *et al.* (U.S. Patent No. 5,283,173) in view of any one of Erickson *et al.* (U.S. Patent No. 5,525,490), Korsmeyer (U.S. Patent No. 5,834,209) or Gallatin *et al.* (U.S. Patent No. 5,837,478) and further in view of Wood (U.S. Patent No. 5,641,641).

Fields *et al.* teaches (see entire document) the yeast two hybrid system in which a first peptide of a binding pair is fused to the DNA binding domain of a transcriptional activation protein and the second peptide of a peptide binding pair is fused to the activation domain of a transcriptional activation protein and the binding of the two fusion proteins results in the expression of a reporter gene. The peptides of the binding pair can be any protein, including cell surface receptors and their ligands, such as growth factors (column 3, lines 57-60). The yeast can be *Saccharomyces cerevisiae* or *Schizosaccharomyces pombe* (column 6, lines 15-17). The

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transcriptional activation protein can be Gal4, Gcn4 or Adr1 (column 4, lines 62-66). The host strain carries a deletion of the transcriptional activation protein (column 6, lines 65-68). The fusion proteins can be expressed from autonomously-replicating plasmids (column 5, lines 41-47).

Fields *et al.* does not teach the use of luciferase as a reporter gene or the use of a heterologous DNA binding protein such as lexA. Erickson *et al.* (column 3, lines 15-48), Korsmeyer (column 42, lines 17-41) and Gallatin *et al.* (column 7, lines 39-67) each teach the yeast two hybrid assay and disclose that luciferase can be used in the two hybrid assay as a reporter gene. Wood (entire document) provides detailed guidance on the use of luciferase, particularly *Photinus* luciferase, as a reporter gene in many cell types, including yeast. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute luciferase as a reporter gene into the yeast two hybrid assay of Fields *et al.*, motivated by the teachings of Erickson *et al.*, Korsmeyer or Gallatin *et al.* that luciferase can be used in the two hybrid assay and further motivated by Wood which teaches the ease with which luciferase can be assayed. One of ordinary skill in the art would reasonably expect that luciferase would function as a reporter gene in the yeast two hybrid assay based on the teachings of Erickson *et al.*, Korsmeyer or Gallatin *et al.* as to the equivalence of different reporter genes in the assay.



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Erickson *et al.* (column 5, lines 16-45) and Gallatin *et al.* (column 8, lines 42-60) teach the use of *lexA* as the DNA binding domain in the yeast two hybrid assay. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the DNA binding domain of *lexA* into the yeast two hybrid assay of Fields *et al.* based on the teachings of Erickson *et al.* or Gallatin *et al.* as to the equivalence of the *lexA* DNA binding domain and other DNA binding domains.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-136 of copending Application No. 09/305,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to yeast cells for use in a two hybrid assay and which comprise luciferase as a reporter gene, while the claims of 09/305,483 are drawn to the same yeast cells but encompassing any reporter gene, including luciferase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Conclusion*

Claims 1-42, 44, 52 and 58-69 are rejected. Claims 43, 45-51 and 53-57 are allowable. Claims 12, 15-28, 40 and 43-69 are free of the prior art as the prior art does not teach the use of

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*Renilla* luciferase in yeast and does not teach the use of low copy number plasmids in the yeast two hybrid assay.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Schwartzman whose telephone number is (703) 308-7307. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-3014.

Any inquiry of a administrative or procedural nature or relating to the status of this application or proceeding should be directed to Dianiece Jacobs, Patent Analyst, whose telephone number is (703)-305-3388.

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER

June 30, 2001